UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,032	02/09/2005	Chise Mukaidani	2004 1544A	1374

513 7590 02/17/2006

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,032	MUKAIDANI ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 7-11, and 16-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is administered a complement inhibitor.

Group II, claim(s) 1, 2, 7-11 and 16-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient hepatopathy X DAF/CD55 transgenic mating.

Group III, claim(s) 1,2,7-11 and 16-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient hepatopathy X DAF/CD55 transgenic mating and wherein said mouse is administered a complement inhibitor.

Group IV, claim(s) 1-4, 7-10, 12, 13, and 16-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient mouse X hepatopathy mouse mating.

Group V, claim(s) 1, 5, 7-10, 14, and 16-18, drawn to a method for proliferating human hepatocytes in the liver of a hemizygous immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient mouse X hepatopathy mouse mating and wherein the mouse is administered hepatocyte growth factor before transplanting human hepatocytes into them.

Group VI, claim(s) 1, 6-10, and 15-18, drawn to method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is administered a complement inhibitor and wherein the mouse is treated with a anti-Fas antibody.

Group VII, claim(s) 1, 6-10, and 15-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient hepatopathy X DAF/CD55 transgenic mating and wherein the mouse is treated with anti-Fas antibody.

Group VIII, claim(s) 1, 6-10, and 15-18 drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient hepatopathy X DAF/CD55 transgenic mating and wherein said mouse is administered a complement inhibitor and wherein the mouse is treated with anti-Fas antibody.

Group IX, claim(s) 1, 6-10 and 15-18, drawn to a method for proliferating human hepatocytes in the liver of a immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient mouse X hepatopathy mouse mating and wherein the mouse is treated with anti-Fas antibody.

Group X, claim(s) 1, 6-10, and 15-18, drawn to a method for proliferating human hepatocytes in the liver of a hemizygous immunodeficient hepatopathy mouse, wherein said mouse is the progeny of immunodeficient mouse X hepatopathy mouse mating and wherein the mouse is administered hepatocyte growth factor before transplanting human hepatocytes into them and wherein the mouse is treated with anti-Fas antibody.

Group XI, claim(s) 19-20 and 24-26, drawn to a method of isolating human hepatocytes from the liver of a chimeric mouse transplanted with said human hepatocytes.

Group XII, claim(s) 21-23, drawn to a chimeric mouse carrying in their live transplanted human hepatocytes.

Group XIII, claim(s) 27 and 28, drawn to isolated human hepatocytes obtained from a mouse transplanted with said hepatocytes.

Group XIV, claim(s) 29, drawn to a hybrid-type artificial liver filled with the human hepatocytes were growth in the a mouse liver.

Group XV, claim(s) 30-32, drawn to a monoclonal antibody recognizing human hepatocytes and the K8216 (FERM BP-8333) hybridoma that produces said antibody.

Group XVI, claim(s) 33, drawn to a method for testing pharmaceutical kinetics or toxicity of a candidate substance, which comprises systemically administering the substance to a chimeric mouse transplanted with human hepatocytes.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.
2) A product and a process of use of said product.
3) A product, a special process of manufacture of said product, and a process of use of said product.
4) A process and an apparatus specially designed to carry out said process.
5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The instant inventions are drawn to multiple products and multiple methods of use and make the various products

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

Also, the requirement that a technical feature be special is not met because it is anticipated by Dandri et al (Hepatology 33(4)981-8, 2001) and therefore represents a lack of unity in these inventive entities. to be examined even though the requirement be traversed (37 CFR 1.143).

The instant invention of claim 1 is drawn to a method of growing human hepatocytes in the liver of a immunodeficient hepatopathy mouse.

Dandri et al discloses the production of immunodeficient hepatopathy mice whose liver was repopulated with human hepatocytes (abstract).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CRF 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcia S. Noble